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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,401	01/11/2006	Yi Yan Yang	6565-73089-01	1799

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KLARQUIST SPARKMAN, LLP
121 SW SALMON STREET
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PORTLAND, OR 97204

EXAMINER

GULLEDGE, BRIAN M

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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07/13/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/564,401	Applicant(s) YANG ET AL.	
	Examiner Brian Gullede	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-45 is/are pending in the application.
- 4a) Of the above claim(s) 21-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/27/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Previous Rejections

Applicants' arguments, filed 27 April 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement filed 27 April 2010 is acknowledged. However, the non-patent literature reference (the Chinese office action) cited by said statement was not considered by the Examiner, as a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of this non-English language document was not provided, as required by 37 CFR 1.98(a)(3).

Also, Applicant requests that the information disclosure statement filed 10 June 2009 be considered, stating that the information disclosure statement included a deposit account charge authorization to satisfy the fee requirement. The Examiner has not considered this information disclosure statement, as the fee was not been paid, as required by 37 CFR 1.97(c). The Applicant did not state that the fee, as set forth in 37 CFR 1.17(p), should be paid.

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Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 has been amended to recite that the polymer exhibits a “discontinuous swelling ratio around a lower critical solution temperature.” It is unclear what this claim is reciting. A ratio compares at least two different values or states, and the claim does not define or state what is compared for determining this ratio. For purposes of examination, the limitation will be taken to refer to the swelling ratio of a membrane prepared from the polymer, comparing the dried state to the fully hydrated state at various temperatures.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al. (*Polymer*, 1997, 38(21), pages 5339-5345) in view of Vakkalanka et al. (*Polymer Bulletin*, 1996, 36, pages 221-225). Applicant argues that the rejection is not proper. Applicant states that the Vakkalanka et al. reference does not suggest the polymer have the instantly recited feature that the polymers exhibit a discontinuous swelling ratio around a lower critical solution temperature. Applicant also states there is no reason for the skilled artisan to expect this outcome.

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Applicant further refers to the supposedly enclosed Allen et al. reference. Applicant states that Allen et al. describes polymers for use as cell growth substrates with various ratios of NIPAAm and NtBAAm, and teaches that NtBAAm has a negative effect on the ability of the polymers to support cell growth. And as the present application describes thermosensitive nanoporous polymers useful as wound dressings and as a vehicle for delivery of cells to graft sites, it is pertinent for relating to the contention that the amount of the monomer present in the prior art could be increased.

The Examiner is not persuaded by these arguments. While the references cited by above do not recognize the polymer as "exhibiting a discontinuous ratio around a lower critical solution temperature," the Examiner contends that the polymers prepared by the taught process would possess this property. The instant specification discloses that the discontinuous decrease of swelling ratio is likely affected by the lowest critical solution temperature of the PNIPAAm (paragraph [97]). The instant specification also states that this property is shown by the swelling ratios presented in figure 3, a figure that shows that the relationship between temperature and the swelling ratio is not exactly linear (there is a "kink" in the line fitted to the data). The polymer taught by the references have PNIPAAm, and thus for this reason would have the requisite swelling ratio, as this is the only required component taught by the specification to be needed. Also, the swelling ratios disclosed by Vakkalanka et al. (figures 1 and 2) appear to not be continuous (true linear fit), but rather, like the instantly disclosed figure, have kinks present in the trend, also supporting the conclusion that they possess the instantly recited property.

As for the discussion of Allen et al., the Examiner notes that this reference has not been provided. However, it is unclear how this reference would pertain to the rejection, even if it

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were provided. The claims do not recite a method of using the polymer as a wound dressing, nor do the references cited above (Gan et al. and Vakkalanka et al.) discuss the polymer as a wound dressing. The claims recite a process for preparing a polymer. There is no requirement for the rejection to meet limitations not recited by the claims. See MPEP 2145(VI). So the discussion of the Aller et al. reference that was not provided does not seem pertinent to the claims.

Claims 14-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al. (*Polymer*, 1997, 38(21), pages 5339-5345) and Vakkalanka et al. (*Polymer Bulletin*, 1996, 36, pages 221-225) as applied to claim 13 above, and further in view of Liu et al. (*Langmuir*, 1997, 13(24), pages 6421-6426). The Applicant argues that the rejection is not proper because Liu et al. does not compensate for the defect in the combination of Gan et al. and Vakkalanka et al. discussed above. The Applicant also argues that the amounts instantly recited are not obvious in view of the references, as *In re Peterson* does not pertain to the instant rejection, and that the amounts taught by the different references are not consistent with each other.

The Examiner is not persuaded by these arguments. First, the Examiner is not persuaded that Liu et al. needs to compensate for a defect in the combination of Gan et al. and Vakkalanka et al., as discussed with regards to the rejection of instant claim 13 over those two references. As for the amounts, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. See MPEP 2144.05(I). Here, the ranges taught by Gan et al. generally overlap the claimed ranges. There was no statement that the polymers taught by each reference were being combined and must have similar amounts. Rather,

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Vakkalanka et al. was cited for the addition of one monomer to the polymer, in order to impart a desired property, and Liu et al. was cited for discussions with regards to controlling pore size to affect a different property. The Examiner does not agree that the fact that some of the polymers taught by Vakkalanka et al. and Liu et al. have other amounts for one or two of the components of the polymers (often because there are fewer total components present) renders the rejection improper.

Claims 1 and 3-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al. (*Polymer*, 1997, 38(21), pages 5339-5345) in view of Lee et al. (*J. Appl. Polymer Sci.*, 1999, 71, pages 221-231). Applicant argues that the rejection is not proper. Applicant states that Lee et al. does not suggest the polymer have the instantly recited feature that the polymers exhibit a discontinuous swelling ratio around a lower critical solution temperature, and in fact Lee et al. suggests that the polymers exhibit a continuous swelling ratio (referring to figures 1, 3, and 4 of Lee et al.). Applicant further refers to the Allen et al. reference.

The Examiner is not persuaded by these arguments. While the references cited by above do not recognize the polymer as "exhibiting a discontinuous ratio around a lower critical solution temperature," the Examiner contends that the polymers prepared by the taught process would possess this property. The instant specification discloses that the discontinuous decrease of swelling ratio is likely affected by the lowest critical solution temperature of the PNIPAAm (paragraph [97]). The instant specification also states that this property is shown by the swelling ratios presented in figure 3, a figure that shows that the relationship between temperature and the swelling ratio is not exactly linear (there is a "kink" in the line fitted to the data). The polymer

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taught by the references have PNIPAAm, and thus for this reason would have the requisite ratio, as this is the only required component taught by the specification to be needed. Also, the swelling ratios disclosed by Lee et al. (figures 3 and 4) appear to not be continuous (true linear fit), but rather, like the instantly disclosed figure, have kinks present in the trend. The Examiner disagrees that these demonstrate continuous swelling, and in fact are similar in shape and trend as instantly disclosed figure 3. As for the discussion of Aller et al., the Applicant provides no specific arguments with regards to this rejection, and the Examiner refers to the discussion of Aller et al. above.

Claims 14-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al. (*Polymer*, 1997, 38(21), pages 5339-5345) and Lee et al. (*J. Appl. Polymer Sci.*, 1999, 71, pages 221-231) as applied to claim 13 above, and further in view of Liu et al. (*Langmuir*, 1997, 13(24), pages 6421-6426). The Applicant argues that the rejection is not proper because Liu et al. does not compensate for the defect in the combination of Gan et al. and Lee et al. discussed above. The Applicant also argues that the amounts instantly recited are not obvious in view of the references, as *In re Peterson* does not pertain to the instant rejection, and that the amounts taught by the different references are not consistent with each other.

The Examiner is not persuaded by these arguments. First, the Examiner is not persuaded that Liu et al. needs to compensate for a defect in the combination of Gan et al. and Lee et al., as discussed with regards to the rejection of instant claim 13 over those two references. As for the amounts, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. See MPEP 2144.05(I). Here, the ranges taught by

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Gan et al. generally overlap the claimed ranges. There was no statement that the polymers taught by each reference were being combined and must have similar amounts. Rather, Lee et al. was cited for the addition of one monomer to the polymer, in order to impart a desired property, and Liu et al. was cited for discussions with regards to controlling pore size to affect a different property. The Examiner does not agree that the fact that some of the polymers taught by Lee et al. and Liu et al. have other amounts for one or two of the components of the polymers (often because there are fewer total components present) renders the rejection improper.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gullledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612